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## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

GUID.058PA (02-030)

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on 07/16/2007

Signature Rennae Johnson

Typed or printed name Rennae Johnson

Application Number

10/642,998

Filed

08/18/2003

First Named Inventor

Hatlestad et al.

Art Unit

3714

Examiner

Crabtree, J.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest.  
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)

☒ attorney or agent of record.  
Registration number 50,495

☐ attorney or agent acting under 37 CFR 1.34.  
Registration number if acting under 37 CFR 1.34 \_\_\_\_\_

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07/16/2007  
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.  
Submit multiple forms if more than one signature is required, see below.

☒ \*Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**SERIAL NO. 10/642,998**

**PATENT APPLICATION**

**IN THE UNITED STATES PATENT & TRADEMARK OFFICE**

Appellant:	Hatlestad et al.	Examiner:	Crabtree, J.
Serial No.:	10/642,998	Group Art Unit:	3714
Filed:	August 18, 2003	Docket No.:	GUID.058PA (02-030)
Title:	Sleep Quality Indicators Based on Implanted Device Sensing		

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this Transmittal Letter and the papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on July 16, 2007.

By:   
Rennae Johnson

**APPELLANT'S STATEMENT IN SUPPORT OF  
PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This statement is presented in compliance with the USPTO OG Notice of 12 July 2005 on New Pre-Appeal Brief Conference Pilot Program. Appellant requests a pre-appeal brief conference on the belief that the rejections of record are clearly not proper and without basis. Appellant's request is based upon a clear legal or factual deficiency in the rejections, rather than an interpretation of the claims or the prior art teachings. As such, Appellant believes this request for pre-appeal brief review is appropriate.

Claims 1-12, 14, and 35-46 each stand rejected under 35 U.S.C. §103(a) based upon at least a combination of U.S. Patent No. 6,641,542 to Cho *et al.* (hereinafter "Cho") in view of U.S. Patent No. 5,245,995 to Sullivan *et al.* (hereinafter "Sullivan"). Dependent claim 6 is rejected in view of the above combination and in further view of U.S. Patent No. 5,146,918 to Kallok *et al.* (hereinafter "Kallok"). Previously rejected claims 47-56 have been canceled to place the application in better condition for appeal.

While Appellant would present multiple issues on appeal, the purpose for submitting this request for review concerns a §103(a) rejection of independent claims 1 and 35 that is insufficiently supported by references teaching or suggesting all elements of the claims. The issue currently presented is whether mere mention of “background sound sensor” and “background noises” in a reference constitutes a teaching or suggestion of detecting a non-physiological condition that affects the sleep quality of a patient, and implantably collecting and implantably storing sleep quality data based on the detected condition, as recited in independent claims 1 and 35.

Each of the §103(a) rejections in the final Office Action (dated March 15, 2007) are based on a combination of Cho and Sullivan, where Sullivan is used to supply the element of detecting at least one non-physiological condition that affects sleep quality. Sleep quality data is collected and stored based on at least one physiological condition and the at least one non-physiological condition.

To establish a *prima facie* §103(a) rejection, these limitations must be present in Sullivan, as the Examiner admits that these limitations are not found within the Cho reference. (“Cho et al. do not explicitly disclose measuring a non-physiological condition, other than time, comprising an ambient condition external to the patient that affects sleep quality, as recited in the claim” -Page 3 of Final Office Action, mailed 3/15/07). However, the Examiner’s reliance upon the Sullivan reference to cure the admitted deficiencies of Cho is unsupported.

The Office Action states that “Sullivan et al. teach that it is known in the art to detect ambient conditions such as background noises, as part of a method of detecting sleep apnea (Col. 3; lines 3-13).” (Office Action, Page 3). The only portion of Sullivan cited in support of the Examiner’s allegation, Col. 3, Lines 3-13, summarizes International Patent Publication WO/86/05965.

Appellant notes that the cited passage of Sullivan makes reference to “background sound sensors” and “background noises.” (Col. 3, Lines 3-13). Appellant respectfully submits that proper consideration of what the passage describes, and specifically, what is disclosed by the WO/86/05965 reference summarized in the passage, makes clear that

neither Sullivan nor WO/86/05965 teach or suggest detecting a non-physiological condition associated with sleep quality of a patient.

Sullivan, in summarizing WO/86/05965, discloses a method for detecting sleep apnea that involves background sound sensors which sense background noises. However these background noises described by Sullivan and WO/86/05965 are not recognized as affecting the sleep quality of the patient as recited, for example, in Applicant's claims 1 and 35. In contrast, the background noises described by Sullivan are described as being compared to a data base of information to determine if the patient is undergoing a normal or abnormal breathing pattern. (Col. 3, Lines 3-13). WO/68/05965 makes clear that the detection of background noises is used to differentiate between ambient noise and "sounds indicative of breathing activity" (WO/86/05965, page 8, lines 10-13). The processes involving detection of ambient noise described in WO/86/05965 and Sullivan allows for better identification of breathing events, and these processes are not used to detect noise or any other non-physiologic condition that is recognized as affecting the patient's sleep quality.

WO/86/05965 discloses sensing background sounds and comparing the background noise to a respiration signal to filter the background noise out of the respiration signal, resulting in a purer respiration signal for comparison to a respiration signal database. In this way, the sensing of background noises is limited to improving the detection of physiologic conditions (breathing), and is not employed to detect any non-physiologic conditions that affect sleep quality.

The WO/86/05965 reference discusses the use of background noise as follows:

Alternatively, the detection of audible sounds can be achieved with a microphone array. With this type of microphone configuration, it is possible to emphasize the desirable acoustic information while at the same time attenuating and/or distorting the unwanted speech or random noise. This is achieved by application of well-known nonlinear signal processing techniques (either preprocessing the analog signals or utilizing techniques that are classified as digital signal processing) to the outputs of two or more microphones (known as a microphone array). The processing of the microphone signals, results in an output signal which enhances the on-center (crib) sounds [of a baby]. This class of nonlinear signal processors, for the outputs of an "array of microphones, emphasizes sounds coming from a particular (on-center) location against a background of other

sounds. These processes completely eliminate any off-center impulsive noise which is non-overlapping at the microphones. (Page 23, Line 34 – Page 24, Line 16; emphasis and clarifying comment added).

WO/86/05965 also mentions the use of background noises on Page 6, Line 33 – Page 7, Line 9; Page 8, Lines 5-13; and Page 12, Lines 4-23, as well. Appellant respectfully submits that WO/1986/05965 uses background noise to enhance detection of a physiologic (breathing) parameter, and does not contemplate background noise as a non-physiological condition itself, nor as a non-physiological condition that affects the sleep quality of the patient. Moreover, the fact that WO/1986/05965 uses sensed background noise only to filter out background noise from sensed breathings sounds clearly demonstrates that WO/1986/05965 is uninterested in collecting and storing sleep quality data which may be based on background noise (or other non-physiological conditions affecting sleep quality) and does not appreciate the significance of sounds as a non-physiological condition that affects sleep quality.

The clear lack of teaching or suggestion of detecting a non-physiological condition that affects sleep quality leads to the analysis that the Examiner has read the brief statement found at col. 3, lines 3-13 of Sullivan (which references WO/86/05965) and, with knowledge of Applicant's claimed invention, has applied hindsight reasoning to conclude that Sullivan teaches detecting a non-physiological signal that affects sleep quality. In reality, Sullivan and WO/86/05965 teach nothing of the sort, instead focusing on the use of an ambient noise sensor to filter background noise from a physiological respiration signal.

Appellant respectfully submits that Sullivan's mere mention of a "background sound sensor" and "background noises" in reference to WO/1986/05965 does not constitute a teaching or suggestion of detecting at least one non-physiological condition associated with sleep quality of a patient, the non-physiological condition comprising an ambient condition external to the patient other than time that affects the sleep quality of the patient, particularly when the actual teachings of the WO/1986/05965 reference are considered. As such, the combination of Cho and Sullivan does not teach each and every element and limitation of independent claims 1 and 35.

In the Advisory Action, the Examiner states that the “examiner reminds applicant that the claim recites the step of ‘detecting’ a non-physiological condition. Sullivan teaches ‘detecting’ a non-physiological condition (background noise), and therefore very clearly reads on the claimed limitation.” (Page 2). Appellant respectfully submits that sensing background noises with a sensor does not constitute detecting a non-physiologic condition that affects the sleep quality of the patient. Appellant further notes that neither reference discloses that sleep quality data is implantably collected and stored based on the detected conditions, as recited in independent claims 1 and 35.

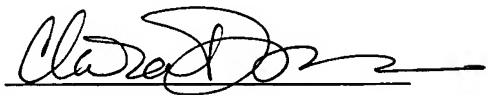
As discussed above, Sullivan is solely relied upon in each of the §103(a) rejections as teaching or suggesting the limitations discussed herein. Because Sullivan does not teach at least these limitations, correspondence to these claim limitations has not been shown. Consequently there is an omission of at least one essential element required for a *prima facie* rejection.

Appellant believes that this statement, when viewed together with the prosecution history, sets forth clear grounds for a finding that the rejections based upon the asserted combination of Cho and Sullivan are improper and without basis.

The undersigned is of record and with authority to prosecute the appeal on behalf of the Assignee.

Respectfully submitted,

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